



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/671,946

09/29/2003

Ashish Varma

PA1436

8308

28390 7590 07/11/2008
MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

MCKANE, ELIZABETH L

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

07/11/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.vasciplegal@medtronic.com

Office Action Summary	Application No. 10/671,946	Applicant(s) VARMA ET AL.	
	Examiner ELIZABETH L. MCKANE	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-13,15 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7-13,15 and 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Prosecution on the merits of this application is reopened on claims 1-3, 5, 7-13, 15, and 17-24 considered unpatentable in view of the newly discovered reference(s) to Clark et al.. Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5, 7-13, 15, and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 2003/0083616) in view of Clarke et al. (US 2006/020967) and Ahlqvist et al. (US 5,881,534).

With respect to claims 1-3, 5, 7-13, 15, 17, and 20-24, Lee et al. teaches a method of sterilizing a catheter balloon susceptible to degradation by ionizing radiation. The balloons are fabricated from polyether block amides (PEBAX). In the method of Lee et al., the balloon is packaged in the sealed interior space of a package **32** capable of providing a barrier to atmospheric oxygen wherein the package includes a first layer including a plastics coated foil and a porous second layer (paragraph [0026]). The balloon and the package are evacuated down to 50 mTorr to remove all air and oxygen from the balloon and package and the package backfilled with nitrogen. See paragraphs [0008-0009]. The level of vacuum disclosed by Lee et al. in combination with the nitrogen flush would have intrinsically been capable of reducing the oxygen

content to the level claimed. To sterilize the balloon, the balloon within the container is exposed to electron beam radiation at a dose of 3-10 Mrad (30-100 kGy). See paragraph [0024]. Lee et al. is silent with respect to a the second layer having the claimed porosity or a third layer including a plastics-coated foil. Lee et al. is further silent to placing an oxygen absorber in a second sealed space within the package.

Clark et al. teaches that it was known in the art at the time of the invention to package a stent delivery device (catheter) in a package comprising first and third layers of plastics-coated foil and an internal layer of breathable Tyvek. See claim 13. An oxygen scavenger is placed in the package within a separate compartment, the package flushed with an inert gas, sealed, and sterilized with gamma radiation. See paragraphs [0017]-[0022]; [0033]. As Clark et al. employs the same breathable layer as that used by the instant invention, it would necessarily have the claimed porosity of 18-240 seconds by the Gurley porosimeter test. It would have been obvious to one of ordinary skill in the art to use the packaging of Clark et al. for sterilization of the catheter of Lee et al., as the packaging of Clark et al. is an easily handleable unitary packaging suitable for containing both the medical device and the oxygen scavenger.

Although Clark et al. discloses that either an oxygen scavenger or a moisture scavenger can be added to the package prior to irradiation, there is no disclosure of why an oxygen scavenger would be used instead of a moisture scavenger. Ahlqvist et al., however, discloses a method of sterilization of sensitive polymeric medical devices wherein the devices are placed within sealed packages along with an oxygen absorber (contained within a second sealed interior space) and irradiated with electron beam

radiation. See col.6, line 48 to col.7, line 21. The oxygen absorber is effective to assure low-oxygen conditions of the sealed package during extended periods of storage. Thus, for this reason it would have been obvious to one of ordinary skill in the art at the time of the invention to use an oxygen scavenger within the sealed package of Lee et al. with Clark et al. to remove essentially all of the oxygen from the sealed package.

As to claims 18 and 19, Lee et al. is silent to the use of gamma radiation as the energy source. However, Ahlqvist et al. discloses that both electron beam and gamma radiation were known in the art at the time of the invention for the sterilization of polymeric medical articles. See col.1, lines 19-28. Similarly, Clark et al. teaches the sterilization of catheter using gamma radiation. See paragraph [0020]. Furthermore, Ahlqvist et al. teaches applying the gamma radiation to the articles at a dose rate of 0.1 Mrad/hr (1 kGy/hr). See col.7, lines 33-36. It would have been obvious to one of ordinary skill in the art to employ gamma radiation as the energy source in the method of Lee et al. since Ahlqvist et al. teaches that gamma radiation and e-beam radiation are functional equivalents in the art of polymeric medical article sterilization. Moreover, it would have been obvious to choose the dose rate disclosed by Ahlqvist et al. as it has been shown to be safe and effective in the sterilization of sensitive medical articles.

Response to Arguments

4. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**/Elizabeth L McKane/
Primary Examiner, Art Unit 1797**

elm
2 July 2008